LIBELED: 4–30–57, Dist. Colo.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective in the treatment for ulcers.

DISPOSITION: 6–10–57. Default—destruction.

DRUGS FOR VETERINARY USE

5399. Cal-Ruphenol. (F. D. C. No. 40295. S. No. 59–056 M.)

QUANTITY: 1 drum containing 65,000 tablets at Philadelphia, Pa., in possession of Cal-Vet Laboratories.

SHIPPED: 4–21–55, from Camden, N. J.

LABEL IN PART: (Drum) "Mannitol * * * with Phenobarbital and Rutin * * * Each tablet contains: Phenobarbital ¼ gr. * * * Mannitol Hexanitrate ½ gr. Rutin 20 mg."

ACCOMPANYING LABELING: Loose labels reading, in part, "Cal-Ruphenol Each tablet contains: Mannitol Hexanitrate 0.5 gr. Phenobarbital 0.25 gr. * * * Rutin 20 mg."

RESULTS OF INVESTIGATION: The loose labels were printed locally for the consignee. They were used in the regular course of business by the consignee in repacking the bulk tablets into containers holding either 1,000 tablets or 100 tablets.

LIBELED: 5–29–57, E. Dist. Pa.

CHARGE: 502 (a)—while held for sale, the labeling of the article, namely, the label used on the repacked tablets, accompanying the article, contained representations that the article was an adequate and effective treatment for preventing and treating chorea in dogs, whereas the article was not an adequate and effective treatment for such purposes.

DISPOSITION: 8–23–57. Default—destruction.

5400. Dr. Mayfield Liquid Roundwormer. (F. D. C. No. 40110. S. No. 56–822 M.)

QUANTITY: 11 1-pt. btls., 18 1-qt. btls., and 1 1-gal. btl. at Mabel, Minn.

SHIPPED: Between 10–31–56 and 2–27–57, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: "Dr. Mayfield Liquid Roundwormer * * * Active Ingredients: Piperazine Hexahydrate 38% Inert Ingredients: Water 62%."

LIBELED: 3–29–57, Dist. Minn.

CHARGE: 502 (a)—when shipped, the bottle labels of the article contained false and misleading representations that the article was an adequate and effective treatment for the removal of cecal worms from chickens; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 6–25–58. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5381 TO 5400

PRODUCTS

	N. J. No.		N. J. No.
Aphrodisiac	5381–5384	Broth, concentrated	[1] 5385
Appetum	5386	Cabbage, desiccated	5398

[1] (5385) Prosecution contested. Contains opinions of the courts.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5401–5420

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings which were terminated with the entry of consent or default decrees of condemnation. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 2, 1959.*

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*For presence of a habit-forming narcotic without warning statement, see No. 5401; omission of, or unsatisfactory, ingredients statements, No. 5403; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5403; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5403.

492730—59

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5401–5420

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its purity or quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5401. Elixir Albephen, Merhistin expectorant, elixir Merbutal, and elixir Duophen. (F. D. C. No. 40337. S. Nos. 67–474 M, 67–476 M, 67–478/9 M.)

QUANTITY: 20 1-gal. btls. and 43 1-pt. btls. of *elixir Albephen;* 68 1-pt. btls. of *Merhistin expectorant;* 6 1-gal. btls. and 94 1-oz. btls. of *elixir Merbutal;* and 246 1-oz. btls. of *elixir Duophen*, at Silver Spring, Md., in possession of Meredyth Co.

SHIPPED: Between 5–5–54 and 1–30–57, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Elixir Albephen Each 5 cc * * * contains Phenobarbital ¼ gr., Hyoscyamine Sulfate 0.104 mg., Atropine Sulfate 0.0195 mg., Hyoscine Hydrobromide 0.0065 mg., Alcohol 23%," "Merhistin Expectorant Each 30 cc * * * contains: Ephedrine Sulfate 40 mg., Citric Acid 3 gr., Merhistin Maleate 225 mg.," "Elixir Merbutal Each 5 cc * * * contains: * * * Sodium * * * Butyl barbiturate 3 grs.," and "Physicians Sample * * * Elixir Duophen Each 30 cc contains: Sodium pentobarbital 1 gr. * * * Phenobarbital 1 gr."

ACCOMPANYING LABELING: A number of loose labels for use in repacking the *elixir Albephen*, some of which were the same as the Albephen label described above and some of which read, in part, as follows: "Elixir Albephen Each Ounce contains: D. Amphetamine Sulfate 15 mg., Thiamin HCL 30 mg., Riboflavin 2.7 mg., Niacin 40 mg., Alcohol 10%."

RESULTS OF INVESTIGATION: The articles in the 1-pt. and 1-oz. btls. were repacked by the consignee from bulk stock which had been shipped as described above. The *elixir Albephen* and *elixir Merbutal* in the 1-gal. btls. represented

the bulk stock of those articles which had not been repacked as of the time of seizure.

LIBELED: 6–26–57, Dist. Md.

CHARGE: 501 (c)—the strength of the *elixir Merbutal*, while held for sale, differed from that which it was represented to possess, namely, 3 grains of butabarbital sodium per each 5 cc. (examination showed that the article contained about 80 percent less than the declared amount of butabarbital sodium); 502 (a)—the labeling of the *elixir Albephen*, while held for sale, namely, the labels intended for use in repacking the article, contained statements representing and suggesting that the article contained d. amphetamine sulfate, thiamine, riboflavin, and niacin, which statements were false and misleading since the article did not contain those ingredients; 502 (d)—the *elixir Merbutal*, while held for sale, contained a derivative of barbituric acid, and the label of the article, while held for sale, failed to bear in juxtaposition with the name and quantity of such derivative the statement "Warning—May be habit forming"; and 503 (b) (4)—the *elixir Albephen* (1-pt. btls.), *Merhistin expectorant*, and *elixir Duophen* were drugs subject to 503 (b) (1), and, while held for sale, their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that another article, vitamin tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–24–57. Consent—claimed by Meredyth Co. The drugs were relabeled.

5402. Vitamin capsules. (F. D. C. No. 40238. S. No. 65–996 M.)

QUANTITY: 12 100-capsule btls., 21 50-capusle btls., and 13 30-capsule btls. at San Francisco, Calif.

SHIPPED: 11–13–56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Bulk container) "NRC No. 2 Therapeutic Vitamin Formula Each Capsule Contains: Thiamin HCL 10 Mgm. Riboflavin 10 Mgm. Niacinamide 100 Mgm. Calcium Pantothenate 20 Mgm. Pyridoxine HCL 2 Mgm. Folic Acid 1.5 Mgm. Ascorbic Acid 300.0 Mgm. Vitamin K 2 Mgm. Vitamin B–12 * * * 4.0 Mcgm."

RESULTS OF INVESTIGATION: The article was shipped in a bulk container from Philadelphia, Pa., and upon arrival at San Francisco, Calif., was repacked and relabeled by the consignee.

Analysis showed that the article contained a significant amount of estrogenic hormone.

LIBELED: 5–6–57, N. Dist. Calif.

CHARGE: 501 (c)—the quality and purity of the article, when shipped, differed from that which it purported to possess; 501 (d) (2)—an estrogenic hormone had been substituted in part for vitamins; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was subject to 503 (b) (1) (B), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5–21–57. Default—destruction.